

were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (5,893,852) in view of Charzewski, and further in view of Humphrey et al. (5,992,000). Claims 31, 32, 39, and 40 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605). Claims 29 and 37 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605) in view of Charzewski. Claims 30 and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605) in view of Charzewski, and further in view of Humphrey et al. (5,992,000). Claims 42 and 43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (5,893,852) in view of Charzewski, and further in view of Langstedt (5,935,476). Claims 42 and 43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605) in view of Charzewski, and further in view of Langstedt (5,935,476). Claims 27 and 35 have been amended, and a marked-up copy of the amended claims is enclosed under the title "Marked-up Copy of Amended Claims" New claims 44 and 45 have been added. New claim 44 corresponds to claim 42 prior to the amendment to claim 27 from which it depends. The claim raises no new issues and no new matter has been added by any of the amendments. Claims 42 and 43 have been canceled without prejudice or disclaimer in light of the other amendments made to the application. Applicant addresses each of these rejections under paragraph headings which coincide with the paragraph numbering of the Office Action.

(1)

Applicant has resubmitted the drawings filed May 24, 2002 to the Official Draftsperson.

(3)

In the Final Office Action claims 27, 28, 33-36, and 41 were rejected under 35 U.S.C. 102(e) as being anticipated by Morales (US 5,893,852, henceforth Morales '852). The instant claims recite a plurality of closely spaced dies. Figures 2a and 2b of the instant application illustrate this feature of the dies being closely spaced. The Final Office Action points to member 30 of Fig. 2 in asserting that Morales '852 teaches closely spaced dies. Applicant

disagrees that this shows closely spaced dies. This figure illustrates the substantial gap between teeth/dies 30 of the Morales '852 device. Fig. 5a also shows the substantial spacing between the dies which fit into the slots 66.

In addition, the independent claims 27 and 35 have been amended to recite that there is a plurality of closely spaced wedge-shaped movable dies and that the dies are disposed about a circle and define an aperture. To the extent Morales has an aperture. The aperture is defined by the unmovable portions of the collar in combination with the dies.

Thus Morales '852 does not teach all the elements of claims 27 and 35 or claims dependent therefrom, and as such Morales '852 does not anticipate the instant claims. Applicant respectfully requests that the anticipation rejection be withdrawn.

(5)

Claims 27, 28, 33-36, and 41 were rejected under 35 U.S.C. 102(e) as anticipated by Morales (6,167,605, henceforth Morales '605). Claims 27 and 35 have been amended to include the feature of moving the dies such that the dies exert a uniform force to the stent along the length of the stent contacting portion of the dies so as to reduce the size of the aperture. Morales '605 does not disclose this feature. In using the device of Morales '605, the dies close progressively from one end of the device to the other. As shown in Figs. 2 and 5, when in the open states, the dies flare outward at one end. Because of this, as each die is moved, it moves inward in a non-uniform way. The second end of the die reaches the closed position after the first end of the die has reached the close position. Thus, Morales '605 does not disclose a method in which each die is moved inward uniformly. Because Morales '605 does not teach all the elements of claims 27 and 35 or claims dependent therefrom, Morales '605 does not anticipate the instant claims. Applicant respectfully requests that the anticipation rejection be withdrawn.

(7)

Claims 31, 32, 39, and 40 were rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morales (5,893,852). Claims 27

and 35 are patentable over Morales '852 for the reasons discussed above in paragraph 3. As such dependent claims 31, 32, 39, and 40 dependent therefrom are patentable over Morales.

Morales '852 does not suggest the desirability of having more than four dies. Because there is no suggestion of desirability, an obviousness rejection is improper. (see, e.g., *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984)). Withdrawal of the obviousness rejection is requested.

(8)

Claims 29 and 37 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (5,893,852) in view of Charzewski (4,942,756). As discussed in paragraph 3, Morales '852 does not teach all the elements of independent claims 27 and 35 and therefore does not teach or suggest all of the elements of claims 29 and 37 which depend therefrom. Charzewski does not provide these necessary elements.

In addition, there is no motivation to combine Morales and Charzewski. The Final Office Action does not point to anything in Morales that suggests changing the temperature of the dies and Charzewski, which is directed to a multi-jaw forming press which is used to work the details of complicated forms and for direct extrusion of material (see the title and abstract), does not suggest the specific desirability of changing the temperature or cooling dies when reducing a stent in cross-section. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent a teaching or suggestion supporting the combination. (see e.g. *In re Fine*, 5 USPQ 2d, 1596 (1988) (Fed. Cir. 1989)).

Additionally, with regard to claim 37, the intended function of the crimper would be destroyed by applying the heating element as taught in Charzewski. The instant claim recites the step of cooling the dies. This is in strict contrast to heating the dies. As such, an obviousness rejection is inappropriate. (see e.g. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

Moreover, because Morales and Charzewski are from such diverse arts, stent crimping and extrusion processes, a person of ordinary skill in the art would not look to extrusion

processes in solving problems associated with stent crimping. Thus, an obviousness rejection is inappropriate. (see e.g. *In re Pagliaro*, 657 F.2d 1219, 210 USPQ 888 (CCPA 1981)). For this reason and the reasons listed above the 103(a) rejection is inappropriate. Withdrawal of the rejection is respectfully requested.

(9)

Claims 30 and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (5,893,852) in view of Charzewski, and further in view of Humphrey et al. (5,992,000). As discussed above in paragraph 8, Morales '852 in view of Charzewski does not teach or suggest all the elements of the independent claims, let alone the dependent claims. While Humphrey et al. does teach the use of a stent made of Nitinol, Humphrey et al. does not teach or suggest the elements of the independent claims not taught by Morales or Charzewski and, moreover, does not teach cooling the stent. As such, claims 30 and 38 are not obvious in light of the proposed combination. Withdrawal of the obviousness rejection is requested.

(10)

Claims 31, 32, 39, and 40 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605).

The Final Office Action states that it would have been obvious to one of ordinary skill in the art to use 8 or 16 wedge shaped dies. These claims are patentable over Morales '605 for the reasons discussed above with respect to the independent claims from which they depend. Also, Morales '605 does not suggest the desirability and thus the obviousness of having more than four dies. As discussed above, because there is no suggestion of desirability, an obviousness rejection is improper. (see, e.g., *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984)).

Withdrawal of the obviousness rejection is respectfully requested.

(11)

Claims 29 and 37 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605) in view of Charzewski (4,942,756). Claims 29 and 37 have been amended and are directed to a method comprising the step of cooling the temperature of the dies below ambient temperature. Claims 29 and 37 are patentable over the proposed combination for the same reasons as discussed above in paragraph 5 with respect to the independent claims from which they depend. As discussed in paragraph 5, Morales '605 does not teach all the elements of independent claims 27 and 35 and therefore does not teach or suggest all of the elements of claims 29 and 37 which depend therefrom. Nor does Charzewski provide these elements.

In addition, the intended function of the crimper in claims 29 and 37 would be destroyed by applying the heating element as taught in Charzewski. The instant claims recite the step of cooling the dies below ambient temperature. This is in strict contrast to heating the dies which would change the properties of the stent in a different way than cooling the stent. Any cooling, for the sake of argument, only cools to ambient temperature and not below ambient temperature. As such, an obviousness rejection is inappropriate. (see e.g. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

Additionally, there is no motivation to combine Morales and Charzewski. The Office Action does not point to anything in Morales that suggests changing the temperature of the dies and Charzewski, which is directed to a multi-jaw forming press which is used to work the details of complicated forms and for direct extrusion of material (see the title and abstract), does not suggest the specific desirability of changing the temperature or cooling dies when reducing a stent in cross-section. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent a teaching or suggestion supporting the combination. (see e.g. *In re Fine*, 5 USPQ 2d, 1596 (1988) (Fed. Cir. 1989)).

For the reasons listed above the 103(a) rejection is inappropriate. Withdrawal of the rejection is respectfully requested.

(12)

Claims 30 and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605) in view of Charzewski, and further in view of Humphrey et al. (5,992,000).

As discussed above in paragraph 8, Morales '605 in view of Charzewski does not teach or suggest all the elements of the independent claims, let alone the dependent claims. While Humphrey et al. does teach the known use of a stent made of Nitinol, Humphrey et al. does not teach or suggest the missing elements. As such, claims 30 and 38 are not obvious in light of the proposed combination. Withdrawal of the obviousness rejection is requested.

(13)

Claims 42 and 43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (5,893,852) in view of Charzewski, and further in view of Langstedt (5,935,476). Claims 42 and 43 have been canceled without prejudice or disclaimer in light of the other amendments made herein. The limitation of "cooling the dies" has been incorporated into claims 29 and 37.

In order to be completely responsive, Applicant now makes the same argument for claims 29 and 37 as would have been made for canceled claims 42 and 43 regarding the rejection due to the proposed combination of Morales '852, Charzewski, and Langstedt. We point out that applying the process of Langstedt, which has an initial heating step, to the instant claims could interfere with the functioning of the stent. Langstedt discloses raising the die and thereby the stent to 200 C. This could change the properties of some of the metallic stents and destroy the polymer stents. One skilled in the art would not look to a combination having a function that would destroy the intended function of the instant claims. Thus, the obviousness rejection is improper. (see again e.g. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

In addition, neither Charzewski nor Langstedt teach or suggest any of the missing elements of Morales '852. Moreover, there is no motivation to make the proposed combination. The Office Action has relied on Morales for its disclosure of a stent crimper, on Charzewski for

the disclosure of dies that have a temperature change, and on Langstedt for teaching cooling below ambient temperature. Charzewski is directed to a multi-jaw forming which is used to work the details of complicated forms and for direct extrusion of material (see the title and abstract). Langstedt is directed to a device for heating a press tool using magnetic induction heating. The press tool is mounted in a press for manufacturing products wholly or partially of plastic or composite. Even if the instant claims were directed to a device for reducing stents in cross-section, obviousness would not be conceded but in this case, the claims are directed to a method of reducing a stent in cross-section. There is simply no suggestion in Morales to cool the stent and there is nothing in Morales that would motivate one to turn to Charzewski and Langstedt to solve a problem that hasn't been identified in Morales. In addition, there is no suggestion in Charzewski or Langstedt to cool a stent when reducing it in cross-section.

For the above stated reasons, Applicant believes claims 29 and 37 are not susceptible under 35 U.S.C. 103(a) as being unpatentable over Morales (5,893,852) in view of Charzewski, and further in view of Langstedt (5,935,476).

(14)

Claims 42 and 43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605) in view of Charzewski, and further in view of Langstedt (5,935,476). Claims 42 and 43 have been canceled without prejudice or disclaimer in light of the other amendments made herein. The limitation of "cooling the dies" has been incorporated into claims 29 and 37.

In order to be completely responsive, Applicant now makes the same argument for claims 29 and 37 as would have been made for canceled claims 42 and 43 regarding the rejection due to the proposed combination of Morales '605, Charzewski, and Langstedt. We point out that applying the process of Langstedt, which has an initial heating step, to the instant claims could interfere with the functioning of the stent. Langstedt discloses raising the die and thereby the stent to 200 C. This could change the properties of some of the metallic stents and destroy the polymer stents. One skilled in the art would not look to a combination having a function that

would destroy the intended function of the instant claims. Thus, the obviousness rejection is improper. (see again e.g. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

In addition, neither Charzewski nor Langstedt teach or suggest any of the missing elements of Morales '605. Moreover, there is no motivation to make the proposed combination. The Office Action has relied on Morales for its disclosure of a stent crimper, on Charzewski for the disclosure of dies that have a temperature change, and on Langstedt for teaching cooling below ambient temperature. Charzewski is directed to a multi-jaw forming which is used to work the details of complicated forms and for direct extrusion of material (see the title and abstract). Langstedt is directed to a device for heating a press tool using magnetic induction heating. The press tool is mounted in a press for manufacturing products wholly or partially of plastic or composite. Even if the instant claims were directed to a device for reducing stents in cross-section, obviousness would not be conceded but in this case, the claims are directed to a method of reducing a stent in cross-section. There is simply no suggestion in Morales to cool the stent and there is nothing in Morales that would motivate one to turn to Charzewski and Langstedt to solve a problem that hasn't been identified in Morales. In addition, there is no suggestion in Charzewski or Langstedt to cool a stent when reducing it in cross-section.

For the above stated reasons, Applicant believes claims 29 and 37 are not susceptible under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605) in view of Charzewski, and further in view of Langstedt (5,935,476).

CONCLUSION

In view of the foregoing it is believed that the present application, with pending claims 27-41 and 44-45, is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,

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MARKED-UP COPY OF AMENDED CLAIMS

Please amend claims 27, 29, 35, and 37 as follows:

27. (Amended) A method of reducing a stent in cross-section comprising the steps of
a) providing a plurality of closely spaced wedge-shaped movable dies having a length and
a stent contacting portion, the dies disposed about a circle and forming an aperture;

b) placing a stent within the aperture so as to surround the stent with the dies;
c) moving the dies such that the dies exert a uniform force to the stent along the length of
the stent contacting portion of the dies so as to reduce the size of the aperture[and apply an
inward force to the stent].

29. (Amended) The method of claim 27 further comprising the step of [changing] cooling
the temperature of the dies below ambient temperature.

35. (Amended) A method of reducing a stent in cross-section comprising the steps of
a) disposing a stent in an aperture of a device for reducing a stent in cross-section, the
aperture defined by at least three closely spaced movable dies disposed about the aperture, the
dies having a length and a stent contacting portion;

b) reducing the size of the aperture by moving the dies [inward] such that the dies exert a
uniform force to the stent along the length of the stent contacting portion of the dies so as [, the
dies applying a force to the stent] to reduce the stent in size.

37. The method of claim 35 wherein the stent is cooled below ambient temperature prior to
the moving step.